

Applicant(s): S. Jayaraman
Application No.: 10/696,174
Examiner: S. Gherbi

Remarks

Claims 1, 2, 5-14, 16, 18-22, and 26-33 are presented for the Examiner's review and consideration. Claims 1, 2, 6, 14, 18, 26, and 27 have been amended, and claims 3, 4, 15, 17, and 23-25 have been canceled. Claims 29-33 have been added. Applicant believes the claim amendments, claim additions, and the accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

35 U.S.C. §112 Rejections

Claims 1, 2, 5-13, and 16-25 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner stated that there is no support in the specification for the term "existing" as claimed in 1, 17, and 23. In response, Applicant respectfully submits that this rejection should be withdrawn.

Applicant discloses that the disease process or processes which are prevalent in the vessel wall of the patient are identified. (¶0093). Also, a procedure may be performed with the goal of determining the prevalent disease process. (¶0094). Applicant contends that an "existing" disease process is synonymous with a "prevalent" disease process. That is, both terms describe a disease process that is present in the vascular disease.

To alleviate any confusion in terminology, Applicant has amended "existing" to "prevalent." Support for "prevalent" may be found throughout the specification with emphasis on ¶¶0093-0094. As such, Applicant submits that claims 1, 2, 5-13, 16, 18-22 meet the requirements of §112, first paragraph. Claims 17 and 23-25 have been canceled to expedite prosecution of this case.

Claim 14 was also rejected under 35 U.S.C. §112, first paragraph. The Examiner stated that there is no support in the specification for the primer layer including one of a bioabsorbable polymer and a biostable polymer. In response, Applicant respectfully submits that this rejection should be withdrawn.

Applicant discloses that the primer layer may be made of a bioabsorbable polymer or a

Applicant(s): S. Jayaraman
Application No.: 10/696,174
Examiner: S. Gherbi

biostable polymer. (¶0052). Applicant contends that the claim language "one of a bioabsorbable polymer and a biostable polymer" means one or the other. The term "one of" defines the primer layer as having a bioabsorbable polymer or a biostable polymer. Accordingly, Applicant submits that claim 14 meets the requirements of §112, first paragraph. Nevertheless and in order to expedite prosecution, Applicant has amended claim 14.

Claim 28 was also rejected under 35 U.S.C. §112, first paragraph. Specifically, the Examiner stated that there is no support in the specification for the phrase "wherein coating of the intravascular implant is performed at the procedure site." In response, Applicant respectfully submits that this rejection should be withdrawn.

Applicant discloses that a single procedure may be performed to identify the disease process and insert the coated implant in the patient. In this regard, it is envisioned that the implant could be coated with the desired agent or agents at the site of the procedure. (¶0094). As such, Applicant contends that the phrase "wherein coating of the intravascular implant is performed at the procedure site" is supported by the specification. Applicant submits that claim 28 meets the requirements of §112, first paragraph.

35 U.S.C. §102 Rejection

Claims 1, 5-11, 17, and 23-25 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application Publication No. 20030060877 to Falotico *et al* (hereinafter "Falotico"). In response, Applicant respectfully submits that this rejection should be withdrawn.

Falotico discloses medical devices coated with therapeutic drugs to treat various vascular diseases, for example, restenosis and vulnerable plaque (abstract). Restenosis after percutaneous transluminal coronary angioplasty is a gradual process initiated by vascular injury. Multiple processes, including thrombosis, inflammation, growth factor and cytokine release, cell proliferation, cell migration and extracellular matrix synthesis each contribute to the restenosis process (¶0006). Atherosclerosis is another vascular disease which includes the hardening of the arteries with plaque. This inflamed plaque is known as atherosclerotic vulnerable plaque (¶0023). Given the lack of currently available effective technologies for detecting vulnerable

Applicant(s): S. Jayaraman
Application No.: 10/696,174
Examiner: S. Gherbi

plaque, the treatment of vulnerable plaque is typically initiated only after the plaque has ruptured and clinical symptoms have developed. Detection technologies currently under investigation include refined MRI, thermal sensors, elasticity sensors, intravascular ultrasound, optical coherence tomography, contrast agents, and near-infrared and infrared light. The treatment of vulnerable plaque, however, is preferably as described below (¶0198). Essentially, there are two physiologic processes ongoing in active vulnerable plaque: inflammation and lipid metabolism (¶0199). A stent may include one or more therapeutic agents for treating both the inflammation and lipid metabolism processes (¶0200).

Applicant discloses, *inter alia*, devices and methods for treating a vascular disease (abstract). To treat or prevent a specific disease process of a vascular disease, the disease process or processes which are prevalent in the vessel wall of the patient are identified (¶0093). Techniques used to identify these events or processes include an angiogram, fluoroscopy, CT scan, MRI, intravascular MRI, lesion temperature, genetic determination, etc. (¶0086). Construction of a disease specific therapeutic coating can be designed which can be used to treat or prevent processes of restenosis from people with various risk factors and underlying mechanisms. That is, restenosis is different in every individual depending on the underlying conditions that constitute the vascular disease (¶0092). A therapeutic agent is selected for treating or preventing the identified disease process or processes. An intravascular implant may be coated with a therapeutically effective amount of the therapeutic agent to treat or prevent the disease process (¶0093).

Applicant respectfully contends that Falotico fails to teach or suggest all the elements of the claimed invention. For example, Falotico does not teach the diagnosis of a patient as having a vascular disease in conjunction with the determination of a prevalent disease process of a vascular disease within a specific patient. Rather, Falotico simply lists various disease processes of certain vascular diseases, like restenosis and atherosclerosis. Therefore, Falotico does not select therapeutic agents based on a prevalent disease process nor does he tailor his medical implant to a specific disease process prevalent in a particular patient. In contrast, Applicant teaches the diagnosis of a vascular disease and the determination of a prevalent disease process in

Applicant(s): S. Jayaraman
Application No.: 10/696,174
Examiner: S. Gherbi

a patient and the selection of a therapeutic agent to specifically treat that prevalent disease process. Applicant's implant is tailored to the underlying conditions in an individual patient.

To highlight these distinctions, Applicant has amended independent claims 1 and 18. Applicant respectfully submits that these independent claims are patentable over Falotico. Based on at least their dependencies, Applicant submits that claims 5-11 are patentable as well. Applicant has canceled claims 17 and 23-25. It should be understood that the cancellations are being made to expedite prosecution and should not be construed as an admission that the present invention is not patentable over Falotico.

35 U.S.C. §103 Rejection

Claims 2, 12-14, 16, 18-22, and 26-28 were rejected under 35 U.S.C. §103(a) as being unpatentable over Falotico. Applicant respectfully submits that this rejection should be withdrawn.

The Examiner stated that it would be obvious to one having ordinary skill in the art to examine a patient's background information to determine whether he/she was genetically predisposed for vascular disease. Applicant contends that the present invention is not directed toward a patient's predisposition for a vascular disease. Rather, the present invention teaches using genetic determination to determine a prevalent process in an existing vascular disease of the patient. Testing a patient for the predisposition of a vascular disease would not involve determining a prevalent disease process because a patient predisposed for a vascular disease does not have the vascular disease, but rather has the genes which may or may not lead to the vascular disease.

To highlight this distinction, Applicant has amended claims 2, 12-14, 16, and 18-22 to recite, *inter alia*, that genetic determination is used to identify differently expressed genes in the disease process.

With respect to claims 26-28, the Examiner stated that it is obvious that a surgeon would first "identify" where the disease is located before advancing an implant such as a stent in order to know the correct placement of the device. Applicant respectfully submits that the Examiner

Applicant(s): S. Jayaraman
Application No.: 10/696,174
Examiner: S. Gherbi

has misinterpreted the identification step of the present invention. The step of identifying a prevalent disease process is used in the specification as identifying "what" disease process is prevalent, not "where" the disease process is located. As defined in Merriam-Webster Online Dictionary, "identify" means to establish the identity of. Also, as stated in ¶0094 of the specification, "a procedure may be performed with the goal of determining the prevalent disease process." Therefore, the identification step determines the identity of the prevalent disease process. Finding the location of the vascular disease is not the goal of the identification step. The present invention regards the location of the vascular disease to be predetermined in order to facilitate the determination of a prevalent process of the disease.

To more clearly define the present invention, Applicant has amended claims 26-28 and all base and intervening claims to recite, *inter alia*, determining a prevalent disease process of the vascular disease. Applicant contends that the term "determining" connotes "what" disease process is prevalent, not "where" it is located. As such, Applicant submits that the amended claims overcome the §103 rejection based on Falotico.

Reply to Response to Arguments

In the Office Action, the Examiner stated that "no definition or criticality is associated with the term 'genetic determination' therefore as best understood it is obvious [that] heart disease can be genetically linked as is well documented and this is an obvious identifying factor when diagnosing a patient." As previously explained, the term "genetic determination" as used in the present invention describes the method in which a prevalent disease process is identified or determined. The term is not used to describe a patient's predisposition or genetic linkage to a particular disease. As stated in ¶0094, genetic determination is a technique to identify differently expressed genes in the process of a vascular disease. In the present invention, a patient is diagnosed with having a vascular disease, then, genetically, a prevalent disease process of that vascular disease is determined. The criticality of "genetic determination" is that an existing disease process can be determined.

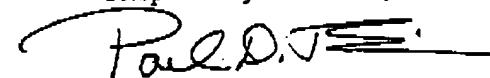
Applicant(s): S. Jayaraman
Application No.: 10/696,174
Examiner: S. Gherbi

Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

A fee of \$395 is believed to be due for the request for continued examination. The fee is being submitted herewith along with PTO-2038, Credit Card Payment Form. Please charge any additional fees (or credit overpayments) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 795-A03-004).

Respectfully submitted,



Paul D. Bianco, Reg. # 43,500

Customer Number: 33771
Paul D. Bianco
FLETT KAIN GIBBONS GUTMAN BONGINI BIANCO
601 Brickell Key Drive, Suite 404
Miami, Florida 33131
Tel: 305-931-9620; Fax: 305-931-9627
e-mail: pbianco@focusonip.com